



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 558

[Docket No. FDA-2013-N-0839]

New Animal Drugs; Withdrawal of Approval of New Animal Drug Applications;

Diethylcarbamazine; Nicarbazine; Penicillin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of three new animal drug applications (NADAs) at the sponsors' request because the products are no longer manufactured or marketed.

DATES: This rule is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6843, email: david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Phibro Animal Health Corp., 65 Challenger Rd., 3d Floor, Ridgefield Park, NJ 07660 has requested that FDA withdraw approval of NADA 098-371 for use of nicarbazine, penicillin, and roxarsone in 3-way, combination drug Type C medicated feeds for broiler chickens and NADA 098-374 for use of nicarbazine and penicillin in 2-way, combination drug Type C medicated feeds for broiler chickens because the products are no longer manufactured or marketed. Accordingly, 21 CFR 558.366 and 558.460 are being

amended to reflect the withdrawal of approval.

R. P. Scherer North America, P.O. Box 5600, Clearwater, FL 33518 has requested that FDA withdraw approval of NADA 123-116 for Diethylcarbamazine Citrate Capsules used in dogs for the prevention of heartworm disease because the product is no longer manufactured or marketed. Accordingly, 21 CFR 520.622d is being amended to reflect the withdrawal of approval.

Following this withdrawal of approval, R. P. Scherer North America is no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for these firms.

Elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADA 098-371, NADA 098-374, and NADA 123-116, and all supplements and amendments thereto, is withdrawn. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. In § 510.600, in the table in paragraph (c)(1), remove the entry for “R. P. Scherer North America”; and in the table in paragraph (c)(2), remove the entry for “011014”.

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.622d [Removed]

4. Remove § 520.622d.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

5. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.366 [Amended]

6. In § 558.366, in the table in paragraph (d), in the entry for “90.8 to 181.6 (0.01 to 0.02 pct)”, remove the entries for “Penicillin 2.4 to 50” and “Penicillin 2.4 to 50 and roxarsone 22.7 to 45.4”.

§ 558.460 [Amended]

7. In § 558.460, remove and reserve paragraph (d)(2)(iv).

Dated: August 19, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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